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Janet D'Annunzio-Ellis

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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

**Applicants** 

Kobayashi et al.

Art Unit:

Not Yet Assigned

Serial No.:

10/526,650

Examiner:

Not Yet Assigned

Filed:

March 3, 2005

Customer No.:

21559

Title:

METHODS OF PRODUCING A VIRAL VECTOR COMPRISING A MEMBRANE PROTEIN THAT BINDS TO SIALIC ACID AS A COMPONENT OF THE ENVELOPE USING NEURAMINIDASE

DERIVED FROM GRAM-POSITIVE BACTERIA

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## INFORMATION DISCLOSURE STATEMENT

Applicants submit the references listed on the enclosed Form PTO-1449, copies of which are enclosed, with the exception of U.S. patents and U.S. patent application publications.

The present application is the U.S. national stage of PCT/JP2003/011299. The following references, which are enclosed, were cited in the International Search Report

POT

for PCT/JP2003/0112. A copy of the International Search Port was submitted in the present U.S. national stage application on March 3, 2005.

Yang et al., "Hemagglutinin Specificity and Neuraminidase Coding Capacity of Neuraminidase-Deficient Influenza Viruses," *Virology* 229(1):155-165 (1997).

WO 01/92508 A1

Sun et al., "Neuraminidase From A Bacterial Source Enhances Both HIV-1-Mediated Syncytium Formation and the Virus Binding/Entry Process," *Virology* 284(1):26-36 (2001).

Bosch et al., "Inhibition of Release of Lentivirus Particles With Incorporated Human Influenza Virus Haemagglutinin By Binding To Sialic Acid-Containing Cellular Receptors," *J. Gen. Virol.* 82(Pt. 10):2485-2494 (2001).

Lin and Cannon, "Use of Pseudotyped Retroviral Vectors to Analyze the Receptor-Binding Pocket of Hemagglutinin From a Pathogenic Avian Influenza A Virus (H7 Subtype)," *Virus Res.* 83(1-2):43-56 (2002).

Kobayashi et al., "Pseudotyped Lentivirus Vectors Derived from Simian Immunodeficiency Virus SIVagm with Envelope Glycoproteins from Paramyxovirus," *J. Virol.* 77(4):2607-2614 (2003).

WO 03/066868 A1

WO 99/13905 A1

WO 01/92508 is written in the Japanese language. English translation of this reference is also enclosed.

Submission of this statement is not a representation that a search has been made, nor is the inclusion of information in this statement an admission that the information is material to patentability.

This statement is being filed before the receipt of a first Office action on the merits.

If there are any charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

Date: 🐰 /

Jan N. Tittel, Ph.D.

Reg. No. 52,290

Clark & Elbing LLP 101 Federal Street Boston, MA 02110

Telephone: 617-428-0200

Facsimile: 617-428-7045



2002/80/10 50026/050001 Methods of Producing A Viral Vector Comprising A Membrane Protein That... Number: 25 Number: Pages: Pages: Date: Pages: Pages: Pages: Pages: Pages: Pages: \*\*\*PROSECUTION\*\*\* D Application Data Sheet D Assignment & Cover Sheet ☐ Preliminary Amendment ☐ Sequence Statement ☐ Sequence Diskette ☐ Sequence Listing ☐ Change of Address □ Declaration & POA ☑ Cited References ⊠ Form PTO-1449 Matter Name: D3-A0204P-US SQI 🔯 The U.S. PTO date stamp sets forth the date of receipt of: Pages: Pages: Pages: Pages: Pages: Pages: Pages: Pages: Pages: March 3, 2005 Kobayashi et al. Serial/Patent Number: 10/526.650-☐ Issue Fee Transmittal Form ☐ Drawings Formal/Informal Transmittal Letter

Transmittel Letter

Notice to File Missing Parts ☐ Reply to Office Action ☐ Reply to Missing Parts Petition for Extension Atty/Secy: INT/ide □ Notice of Appeal ☐ M-Fee Payment ☐ Appeal Brief Applicant/Patentee: Other -Other -Check Other -Filed/Issued: Title:

TITUTE FORM PTO-14

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

INFORMATION DISCLOSURE

STATEMENT BY APPLICANT

(Use several sheets if necessary)

Attorney D No.
Serial No.

50026/050001

10/526,650

Kobayashi et al.

Filing Date

March 3, 2005

Filling Date

Applicant

Not Yet Assigned

Group IDS Filed

July 8, 2005

(37 C.F.R. § 1.98(b))

## U.S. PATENT DOCUMENTS

Examiner's Initials	Document Number	Issue or Publication Date	Patentee or Applicant	Class	Subclass	Filing Date (If Appropriate)
	6,645,760	Nov. 11, 2003	Nagai et al.			
	6,723,532	Apr. 20, 2004	Nagai et al.			
	6,746,860	Jun. 8, 2004	Tokusumi et al.			
	6,828,138	Dec. 7, 2004	Nagai et al.			
	2002/0098576	Jul. 25, 2002	Nagai et al.			
	2002/0002143	Jan. 03, 2002	Kano et al.			
	2003/0170210	Sep. 11, 2003	Masaki et al.			
	2003/0170897	Sep. 11, 2003	Imai et al.			
	2004/0121308	Jun. 24, 2004	Nagai et al.			
	2003/0170266	Sep. 11, 2003	Kitazato et al.			
	2004/0005296	Jan. 8, 2004	Yonemitsu et al.			
	2004/0053877	Mar. 18, 2004	Fukumura et al.			
	2004/0101965	May 27, 2004	Griesenbach et al.			
	2003/0166252	Sep. 4, 2003	Kitazato et al.			
	2003/0203489	Oct. 30, 2003	Yonemitsu et al.			

## FOREIGN PATENTS OR PUBLISHED FOREIGN PATENT APPLICATIONS

Examiner's Initials	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation (Yes/No)
	WO 99/13905 A1	Mar. 25, 1999	WIPO			
	WO 01/92508 A1	Dec. 6, 2001	WIPO			Yes
	WO 02/038726 A2, A3	May 16, 2002	WIPO			
	WO 03/066868 A1	Aug. 14, 2003	WIPO			

**EXAMINER** 

DATE CONSIDERED

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(MODIFIED) PATENT AND TRADEMARK OFFICE					Serial No.		10/526,650		
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	OTHER DOC	JMENTS (INCL	.UDING A	UTHOR, TITLE, [	DATE, PLAC	E OF PUBL	ICATION)		
Agrawal et al., "Cell-Cycle Kinetics and VSV-G Pseudotyped Retrovirus-Mediated Gene Transfer in Blood-Derived CD34* Cells," Exp. Hematol. 24:738-747 (1996).									
	Bosch et al., "Inhibition of Release of Lentivirus Particles With Incorporated Human Influenza Virus Haemagglutinin By Binding To Sialic Acid-Containing Cellular Receptors," <i>J. Gen. Virol.</i> 82(Pt. 10):2485-2494 (2001).								
	Burns et al., "Vesicular Stomatitis Virus G Glycoprotein Pseudotyped Retroviral Vectors: Concentration to Very High Titer and Efficient Gene Transfer into Mammalian and Nonmammalian Cells," <i>Proc. Natl. Acad. Sci. USA</i> 90(17):8033-8037 (1993).								
	Compans et al., "Effect of Antibody to Neuraminidase on the Maturation and Hemagglutinating Activity of an Influenza A <sub>2</sub> Virus," <i>J. Virol.</i> 4(4):528-534 (1969).								
	Dong et al., "A Chimeric Avian Retrovirus Containing the Influenza Virus Hemagglutinin Gene Has an Expanded Host Range," <i>J. Virol.</i> 66(12):7374-7382 (1992).								
	Griffin et al., "Effects of Hexose Starvation and the Role of Sialic Acid in Influenza Virus Release," Virology 125(2):324-334 (1983).								
	Hatziioannou et al., "Incorporation of Fowl Plague Virus Hemagglutinin into Murine Leukemia Virus Particles and Analysis of the Infectivity of the Pseudotyped Retroviruses," <i>J. Virol.</i> 72(6):5313-5317 (1998).								
,	Kobayashi et al., "Pseudotyped Lentivirus Vectors Derived from Simian Immunodeficiency Virus SIVagm with Envelope Glycoproteins from Paramyxovirus," J. Virol. 77(4):2607-2614 (2003).								
	Lin and Cannon, "Use of Pseudotyped Retroviral Vectors to Analyze the Receptor-Binding Pocket of Hemagglutinin From a Pathogenic Avian Influenza A Virus (H7 Subtype)," <i>Virus Res.</i> 83(1-2):43-56 (2002).								
	Liu et al., "Influenza Type A Virus Neuraminidase Does Not Play A Role in Viral Entry, Replication, Assembly, Or Budding," <i>J. Virol.</i> 69(2):1099-1106 (1995).								
	Morrison et al., "Complementation between Avirulent Newcastle Disease Virus and a Fusion Protein Gene Expressed from a Retrovirus Vector: Requirements for Membrane Fusion," <i>J. Virol.</i> 65(2):813-822 (1991).								
	Morse et al., "Optimizing Influenza Hemagglutinin Pseudotyping of Equine Lentiviral Vectors," <i>Mol. Ther.</i> 5(5 Pt. 2):S38(ABSTRACT110) (2002).								
EXAMINER	R DATE CONSIDERED								
	Initial citation consider		through	citation if not in co	nformance a	and not con	sidered. Inc	lude copy of this	

								Sheet 3 Or 3	
SUBSTITUTE FORM PTO-1  U.S. DEPARTMENT OF COMMER (MODIFIED)  PATENT AND TRADEMARK OFF					Attorney D No. 50026/050001			0001	
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INFORMATION DISCLOSURE					Applicant		Kobayash	Kobayashi et al.	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT					Filing Date		March 3, 2005		
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(37 C.F.R. §	1.98(b))				IDS Filed		July 8, 2005		
U.S. PATENTS									
Examiner's Initials	Patent Number	Issue Date	1	Patentee		Class	Subclass	Filing Date (If Appropriate)	
•	FORE	IGN PATENT (	OR PUBLISHED	FOREIGN	PATENT AF	PLICATIO	N		
Examiner's Initials	Document Number					Class	Subclass	Translation (Yes/No)	
OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION)									
	Négre et al., "Characterization of Novel Safe Lentiviral Vectors Derived From Simian Immunodeficiency Virus (SIVmac251) That Efficiently Transduce Mature Human Dendritic Cells," <i>Gene Ther.</i> 7(19):1613-1623 (2000).								
	Palese et al., "Characterization of Temperature Sensitive Influenza Virus Mutants Defective in Neuraminidase," Virology 61(2):397-410 (1974).								
	Sakurada et al., "Clo Gene in <i>Streptomyc</i>	oning, Expression es lividans," J. I	on, and Charact Bacteriol. 174(2	erization of 1):6896-690	the <i>Micromo</i> 03 (1992).	nospora vi	ridifaciens N	euraminidase	
	Schnell et al., "Development of a Self-Inactivating, Minimal Lentivirus Vector Based on Simian Immunodeficiency Virus," <i>Hum. Gene Ther.</i> 11(3):439-447 (2000).								
	Spiegel et al., "Asialoglycoprotein (ASGP-R)-Restricted Gene Transfer by Retroviral Particles Pseudotyped with Sendai Virus F Protein," <i>Hepatology</i> (Abstract 1429) 28:520A (1998).								
	Spiegel et al., "Pseudotype Formation of Moloney Murine Leukemia Virus with Sendai Virus Glycoprotein F," J. Virol. 72(6):5296-5302 (1998).								
	Sun et al., "Neuraminidase From A Bacterial Source Enhances Both HIV-1-Mediated Syncytium Formation and the Virus Binding/Entry Process," <i>Virology</i> 284(1):26-36 (2001).								
	Vzorov and Compans, "Effect of the Cytoplasmic Domain of the Simian Immunodeficiency Virus Envelope Protein on Incorporation of Heterologous Envelope Proteins and Sensitivity to Neutralization," <i>J. Virol.</i> 74(18):8219-8225 (2000).								
	Yang et al., "Hemagglutinin Specificity and Neuraminidase Coding Capacity of Neuraminidase-Deficient Influenza Viruses," <i>Virology</i> 229(1):155-165 (1997).								
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